



## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

#### Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Patent Term Extension and Adjustment

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0020 Patent Term Extension and Adjustment. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

**DATES:** To ensure consideration, comments regarding this information collection must be received on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email:* [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include “0651-0020 comment” in the subject line of the message.
- *Federal Rulemaking Portal:* <https://www.regulations.gov>.
- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Parikha Mehta, Senior Legal Advisor, United States Patent and Trademark

Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-3248; or by email at [parikha.mehta@uspto.gov](mailto:parikha.mehta@uspto.gov) with "0651-0020 comment" in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under "Information Collection Review."

## **SUPPLEMENTARY INFORMATION:**

### **I. Abstract**

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417), which is codified at 35 U.S.C. 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or United States Department of Agriculture (USDA). Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. 156 is 5 years. The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710–1.791.

This information collection covers information gathered in patent term extension applications submitted under 35 U.S.C. 156(d). Under this provision, an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product, or a method of manufacturing the approved product. 35 U.S.C. 156(d) also requires the submission of information that enables the USPTO to determine the eligibility of the patent for extension, and the rights that will be derived from the extension, and information to enable the USPTO and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension. Additionally, 35 U.S.C. 156(d) requires the applicant for patent term extension to provide a brief description of the activities undertaken by the applicant

during the regulatory review period with respect to the approved product and the significant dates of these activities.

This information collection also covers information gathered in requests for interim extensions pursuant to 35 U.S.C. 156(d)(5) and 156(e)(2). Under 35 U.S.C. 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect. Under 35 U.S.C. 156(e)(2), an interim extension may be granted if the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. In addition, this information collection covers requests for review of final eligibility decisions, and requests to withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases adjust the term of an original patent under the provisions of 35 U.S.C. 154 due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse USPTO determination of patentability. The USPTO administers 35 U.S.C. 154 through 37 CFR 1.701–1.705. The patent term provisions of 35 U.S.C. 154(b), as amended by Title IV, Subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, allow the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination. This information collection covers information gathered in such a request.

In addition, this information collection covers information collected when the USPTO reduces the amount of a granted patent term adjustment if delays were caused by an applicant's failure to make a reasonable effort to respond to a communication

from the USPTO within three months of the communication's mailing date. Applicants may petition for reinstatement of a reduction in patent term adjustment with a showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period.

The title of this item has been changed from "Patent Term Extension" to "Patent term Extension and Adjustment" to better reflect the scope of actions available regarding Patent terms that are a part of this information collection.

## **II. Method of Collection**

Electronically, by mail, or hand delivery to the USPTO.

## **III. Data**

*OMB Control Number:* 0651-0020.

*Forms:* None.

*Type of Review:* Extension and revision of a currently approved information collection.

*Affected Public:* Private sector; individuals or households.

*Respondent's Obligation:* Required to obtain or retain benefits.

*Estimated Number of Annual Respondents:* 915 respondents.

*Estimated Number of Annual Responses:* 915 responses.

*Estimated Time per Response:* The USPTO estimates that the responses in this information collection will take the public approximately between 1 hour and 25 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

*Estimated Total Annual Respondent Burden Hours:* 6,113 hours.

*Estimated Total Annual Respondent Hourly Cost Burden:* \$2,659,155.

**Table 1: Total Burden Hours and Hourly Costs to Private Sector Respondents**

Item No.	Item Name	Estimated Annual Respondents  (a)	Respondents per Respondent  (b)	Estimated Annual Responses  (a) x (b) = (c)	Estimated Time per Response (hour)  (d)	Total Annual Hour Burden  (c) x (d) = (e)	Hourly Cost Burden Rate <sup>1</sup>  (f)	Total Annual Cost for Time Spent  (e) x (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156	146	1	146	25	3,650	\$435	\$1,587,750
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	29	1	29	1	29	\$435	\$12,615
3	Petition to review final Eligibility Decision Under 37 CFR 1.750	2	1	2	25	50	\$435	\$21,750
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	8	1	8	20	160	\$435	\$69,600
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	7	1	7	1	7	\$435	\$3,045
6	Response to Requirement to Elect a Single Patent to Extend from a Single Regulatory Review Period	39	1	39	1	39	\$435	\$16,965
7	Response to Request to Identify Holder of Regulatory Approval	2	1	2	2	4	\$435	\$1,740
8	Declaration to Withdraw an Application to Extend Patent Term	1	1	1	2	2	\$435	\$870
9	Petition for Reconsideration of Patent Term Adjustment Determination	631	1	631	3	1,893	\$435	\$823,455
10	Petition for Reinstatement of Reduced Patent Term Adjustment	14	1	14	4	56	\$435	\$24,360
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	4	1	4	2	8	\$435	\$3,480
	<b>Totals</b>	<b>883</b>	<b>---</b>	<b>883</b>	<b>---</b>	<b>5,898</b>	<b>---</b>	<b>\$2,565,630</b>

**Table 2: Total Burden Hours and Hourly Costs to Individual and Household Respondents**

<sup>1</sup> 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg. F-27. The USPTO uses the average billing rate for intellectual property attorneys in private firms which is \$435 per hour.

Item No.	Item Name	Estimated Annual Respondents (a)	Respondents per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hour) (d)	Total Annual Hour Burden (c) x (d) = (e)	Hourly Cost Burden Rate <sup>2</sup> (f)	Total Annual Cost for Time Spent (e) x (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156	4	1	4	25	100	\$435	\$43,500
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	1	1	1	1	1	\$435	\$435
3	Petition to review final Eligibility Decision Under 37 CFR 1.750	1	1	1	25	25	\$435	\$10,875
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	1	1	1	20	20	\$435	\$8,700
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	1	1	\$435	\$435
6	Response to Requirement to Elect	1	1	1	1	1	\$435	\$435
7	Response to Request to Identify Holder of Regulatory Approval	1	1	1	2	2	\$435	\$870
8	Declaration to Withdraw an Application to Extend Patent Term	1	1	1	2	2	\$435	\$870
9	Petition for Reconsideration of Patent Term Adjustment Determination	19	1	19	3	57	\$435	\$24,795
10	Petition for Reinstatement of Reduced Patent Term Adjustment	1	1	1	4	4	\$435	\$1,740
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	1	1	1	2	2	\$435	\$870
	<b>Totals</b>	<b>32</b>	<b>---</b>	<b>32</b>	<b>---</b>	<b>215</b>	<b>---</b>	<b>\$93,525</b>

*Estimated Total Annual Respondent Non-hourly Cost Burden: \$327,003.*

There are no maintenance costs, capital start-up costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total

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<sup>2</sup> Ibid.

annual (non-hour) cost burden for this information collection, in the form of filing fees (\$326,920) and postage (\$83), is \$327,003.

### Filing Fees

The items with filing fees are listed in the table below.

**Table 3: Filing Fees**

Item No.	Item	Annual Estimated Responses	Filing Fee	Total Cost
1	Application to Extend Patent Term Under 35 U.S.C. 156	150	\$1,180	\$177,000
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	10	\$440	\$4,400
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	10	\$230	\$2,300
9	Petition for Reconsideration of Patent Term Adjustment Determination	650	\$210	\$136,500
10	Petition for Reinstatement of Reduced Patent Term Adjustment	15	\$420	\$6,300
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	1	\$420	\$420
	<b>Totals</b>	<b>836</b>	<b>---</b>	<b>\$326,920</b>

### Postage

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service (USPS). The USPTO expects that approximately 1% of the 915 responses in this information collection will be submitted in the mail, resulting in 9 mailed submissions. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be \$9.25. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this information collection will total \$83.

## **IV. Request for Comments**

The USPTO is soliciting public comments to:

- (a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected; and
- (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

**Justin Isaac,**

Information Collections Officer,

Office of the Chief Administrative Officer,

United States Patent and Trademark Office.